DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service

Food & Drug Administration
6751 Steger Drive
Cincinnati, OH 45237-1097

August 18, 1998

Warning Letter
CIN-WL-98-286

CERTIFIED MAIL
RETURN RECEIPT REQUEST

Mal Mixen, President & CEO
Invacare Corporation
One Invacare Way
Elyria, Ohio 44036-2125

Dear Mr. Mixen:

We are writing to you because on April 20/29, 1998 and June 8, 1998, an investigator from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving the product known as the Invacare Venture HomeFill Complete Home Oxygen System which is manufactured and marketed by your firm.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (Act), this product is considered to be a medical device because it is used to diagnose or treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices obtain marketing clearance for their products from FDA before they may offer them for sale. This helps protect the public health by ensuring that new medical devices are shown to be either safe and effective or substantially equivalent to other devices already legally marketed in this country.

Our records do not show that you obtained marketing clearance before you began offering your product for sale. A new premarket notification submission is required for the Invacare Venture HomeFill Complete Home Oxygen System because you have significantly changed or modified your currently marketed oxygen concentrators and have made a major change in the intended use of those devices (see Title 21 of the Code of Federal Regulations, Part 807.81(a)(3)). The Invacare Venture HomeFill Complete Home Oxygen System is intended to be used to transfill cylinders in addition to directly providing oxygen to the patient and represents a major change in intended use, because the devices you are currently marketing are only intended to supply a patient with oxygen. The Invacare Venture HomeFill Complete Oxygen System represents a significant change or modification to your currently marketed devices because it incorporates design changes to accommodate the new intended use that could significantly affect safety or effectiveness. These changes include the addition of a compressor (and the addition of an extra outlet port, regulator, and a valve) and an increase in the maximum oxygen output from 5 liters per minute to 6 liters per minute. The oxygen produced by the Invacare Venture HomeFill Complete Home Oxygen System is a different concentration than that normally found in green oxygen cylinders and does not

meet any known standard. In addition to concerns regarding oxygen concentration, the new device raises safety and effectiveness issues such as the possibility of adulteration of the oxygen output, electromagnetic interference, and patient safety at the increased pressures during transfilling.

It our understanding that you believe that your compressor is not a medical device. Please be advised that the Invacare Venture HomeFill Complete Home Oxygen System and each component of the system is a medical device. For your information, air compressors are classified under 21 CFR 868.6250.

You should know that these violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problem. Please direct your response to Evelyn D. Forney, Compliance Officer, Food and Drug Administration, 6751 Steger Road, Cincinnati, Ohio 45237.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of premarket clearance for your device and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-(800) 638-2041 or through the Internet at http://www.fda.gov.

Sincerely

Carol A. Heppe
Acting District Director
Cincinnati District